REMARKS

Initially, applicant would like to thank the Examiner for the promptly-returned, helpful and courteous telephonic interview he conducted with applicant's undersigned representative on 24 October 2003 regarding the modifications to independent claims 1 and 4 as presented above. During such interview it was indicated that the modifications presented a new issue for consideration by the Examiner, and hence would require filing of an RCE for entry of the Amendment. Correspondingly, applicant is filing an RCE Transmittal concurrently herewith.

Please note that instant Amendment Under 37 CFR 1.116 differs slightly from the Amendment-C Under 37 CFR 1.116 dated 22 October 3002 in that the parentheses have been omitted in the last clause of each of claims 1 and 4.

Upon entry of the present amendment, the claims in the application the claims in the application remain claims 1, 3-11 and 13-21, of which claims 1 and 4 are independent.

Independent claims 1 and 4 are amended to further define that method/apparatus applies light having a wavelength of 700nm – 1100nm (the feature of claim 2, now cancelled) and also involves applying light having a wavelength of 700nm – 1100nm through a ceramic plate (as a reference material) so that the sensed intensity of same can be used as a reference value; while claims 17 and 21 are amended to overcome a minor informality in same, i.e., the "blood sample receptacle" referred to as –blood collection receptacle-- for consistency and proper antecedent basis.

Applicant respectfully submits that the above amendments are fully supported by the original disclosure, including the original claims, the discussion at page 5 relating to the ceramic plate. Applicant further respectfully submits that no new matter is introduced by the above amendments.

Finally, applicant respectfully submits that the above amendments do not raise any new issues for the Examiner because they merely overcome a typographical error, incorporate a feature of a dependent claim into the independent claims, and clarify the ordinary/conventional nature of the blood collection receptacle as previously emphasized in prior amendments and arguments.

Rejection Under 35 USC §102(b)

The Examiner makes final the rejection claims 1-7 and 9-13 under 35 USC §102(b) as being anticipated Soller et al. (US Patent 6,006,119), set forth at item 1 of the Office Action. It

is essentially the Examiner's position that all of the features of the claimed analytical method and apparatus are expressly or inherently disclosed by Soller.

Applicant's Response

Upon careful consideration, and in light of the above amendments to claims 1 and 4, applicant respectfully submits that such rejection is overcome and that each of the present claims is clearly patentably distinct over the Soller reference, based on the following.

Initially, applicant again respectfully submits that Soller's method and apparatus for measuring blood hematocrit does not involve or make obvious the features of amended claims 1 and 4 which make it possible, as a practical matter, to use an ordinary test tube or bag for collecting and analyzing blood samples to determine object characteristics of the blood sample, whereas this distinction represents a tremendous advantage of the present invention over conventional systems.

Generally, a calibration equation is required to be very accurate. For example, when a calibration equation which shows the relationship between the absorbance of a solution in a receptacle and the concentration of a predetermined component is determined, an ideal receptacle (as ideal as practically possible) has been conventionally selected, whereas a receptacle through - with which it is difficult to transmit light has never been selected. Specifically, as mentioned in the present specification, "According to conventional near infrared spectroscopy, near infrared light in a wavelength of 1100nm – 2500nm has been used. It is, therefore, been necessary to prepare a special crystal sample cell with an optical path length of 0.1 – 2mm." Thus when blood is to be analyzed, it has been conventionally necessary to transfer the blood from a collection receptacle into such a special analyzing cell.

Soller's method and apparatus for in vitro testing of blood samples conventionally involves use of a quartz cuvette (see item 1061 in his Fig. 14A), corresponding to the special crystal sample cell, and each sample (whether a reference sample or a tested/unknown sample) is contained in the same quartz cuvette.

In contrast, according to the presently claimed invention, a receptacle with the same specifications as the blood collection receptacle is used for determining a calibration equation.

Since the object of a blood collection receptacle is to contain blood, a blood collection receptacle hardly transmits any light, which prevents an effective spectrum from being obtained. To solve this problem, a specific range of near infrared light, i.e., 700nm – 1100nm, it becomes possible to use a blood collection receptacle to measure a spectrum for determining a calibration equation. That is, the range is significant to use a blood collection receptacle for determining a calibration equation, as well as for collecting/containing blood. Accordingly, the present invention makes it possible (as a practical matter) to analyze blood in the state of being contained in a blood collection receptacle.

In the present invention, a blood sample is analyzed in the state of being contained in a blood collection receptacle which hardly transmits any light, e.g., an ordinary tube or bag. Therefore the intensity of the transmitted light is very low, which causes dispersion in the measurement results. In order to solve this problem, according to the present invention, a reference material (the ceramic plate 12) is employed, and the intensity of the light transmitted through the plate is measured in advance so as to obtain a reference value for sensed measurements. See the bottom of page 5 of the present specification.

Again with reference to the applied patent, while Soller teaches use of near infrared light having a wavelength of 700nm – 1100nm, he chooses such range for a completely different reason as compared to the present invention. Particularly, Soller states that "... 700nm – 1100nm as the latter wavelength range is not significantly absorbed by skin". In other words, the wavelength range is selected to penetrate the skin, noting that Soller specifically pertains to (teaches) a "*Non-invasive* Optical Measurement of Blood Hematocrit (emphasis added)."

Applicant respectfully submits that neither Soller nor any other reference of record teaches or makes obvious the invention as claimed.

Again , applicant respectfully submits that the discussed distinctions are very significant as a practical matter. Even though using a quartz cuvette, as disclosed by Soller, to house a given sample is effective, allowing for determination of an accurate calibration equation and sample measurements, the calibration and sample measurements effected using a plurality of ordinary, interchangeable tubes or bags with the same specifications (the difference in absorbance can be compensated) according to the claimed invention can achieve a useful and substantially accurate

analysis. On the other hand, if the special cuvette is broken by accident or otherwise, then time, labor and added expense are required to adjust the calibration equation to a new cell for continuing an analysis. Also, as a practical matter, the special cuvette cannot be used in an agricultural or factory environment due to the large number of sample objects to be analyzed in such an environment. Since the apparatus according to the present invention uses a plurality of interchangeable (ordinary, inexpensive) test tubes or sample bags, a broken test tube or sample bag can be quickly and easily replaced without need for recalibration, and the apparatus can be efficiently used for quick analyses of liquids in an agricultural or factory environment by an unskilled operator, where such type of analysis is required. See page 9, lines 5-10 of the original specification.

Based on the foregoing, applicant respectfully submits that the rejection of claims 1-7 and 9-13 under 35 USC 102(b) as unpatentable over Soller et al. is overcome, and accordingly it is respectfully requested that such rejection be reconsidered and withdrawn.

Rejections Under 35 USC §103(a)

The Examiner has also rejected the following claims under 35 USC §103(a): claim 8 as being unpatentable over Soller et al. in view of Brown et al. (US Patent 4,134,678), claims 14-16, 19 and 20 as being unpatentable over Soller et al. in view of Kuenstner (US Patent 6,285,448), and claims 14-16, 19 and 20 (? 17 and 21) as being unpatentable over Soller et al. in view of Ikeda et al. (US Patent 4,936,674), as set forth at items 2-4 of the Office Action. It is the Examiner's position that while Soller does not teach a temperature control means as defined in claim 8, analysis of multiple different components of blood, or an optical path length for a blood sample receptacle of 1-2cm: it would have been obvious at the time of the invention to provide Soller's method and apparatus with such a temperature control means based on the teachings of Brown; to analyze multiple different components of blood based on the teachings of Kuenstner, and to provide an optical path length for the blood sample receptacle of 1-2cm based on the teachings of Ikeda.

Applicant's Response

Upon careful consideration, and in light of the above amendments to claims 1 and 4 above, applicant respectfully submits that such rejections are overcome and that present claims 8, 14-17 and 19-21 are clearly patentably distinct over the applied references, based on the foregoing arguments regarding the deficiencies of Soller relative to claims 1 and 4 (which are not overcome by any additional teaching of Brown, Kuenstner and Ikeda), and because the proposed modification of Soller's apparatus relative to a select teaching of the Ikeda reference, as proposed by the Examiner is improperly based on a suggestion coming entirely from the Examiner, rather than from any teaching or suggestion which may be fairly gleaned from the references themselves.

Relative to the proposed modification/combination, Ikeda discloses a special apparatus and method involving a uniquely constructed sample containment chamber for containing a cell suspension , and a rotor disposed in (occupying most of) the chamber with a small gap between the lower surface of the rotor and the bottom surface of the chamber, the rotor is rotated to apply a shear stress to the suspension, a ray transmission path from which a ray is projected into the suspension in the gap, and a transmitted ray detection path from which transmittance from the sample is detected . Ikeda also discussed that an optical path length in the suspension is not smaller than 1cm, such length being defined as "...the shortest distance between the ray transmission path and the transmitted ray detection path in the cell suspension . ..."

On the other hand, while Soller discloses both in vivo measurement and in vitro measurement of hematocrit, the in vitro measurement involving use of the quartz cuvette 1061 which is nothing like Ikeda's special sample containment chamber. Correspondingly, applicant respectfully submits that persons skilled in the art would not consider it obvious to combine/modify Soller's apparatus with Ikeda's sample containment chamber because the references do not provide any motivation for doing so, e.g., the apparatus are structured different to achieve different purposes.

Moreover, applicant respectfully submits that Ikeda's discussed optical path length is distinct from and does not make obvious the claimed feature, i.e., Ikeda's path length pertains to the cell suspension, not to the blood sample (collection) receptacle as claimed.

Based on the foregoing, applicant respectfully submits that the rejections of claims 8, 14-

17 and 19-21 under 35 USC §103(a) based on the applied patents is overcome, and accordingly it is respectfully requested that the rejection be reconsidered and withdrawn.

Other References Cited in the Office Action

The additional references cited by the Examiner on the Form PTO-892 attached to the Office Action (Osten et al., Khalil et al., Proctor et al., Price et al., Shenk et al., and Sonehara et al.) have been considered by applicant, but it is respectfully submitted that these additional references fail to overcome the deficiencies of the applied references as discussed above relative to the claimed invention.

Conclusion

In conclusion, applicant has overcome the Examiner's rejections as presented in the Office Action; and moreover, applicant has considered all of the references of record, and it is respectfully submitted that the invention as defined by each of the present claims is clearly patentably distinct thereover.

Entry of the present Amendment-C is respectfully requested under 37 CFR 1.116 on the grounds that: the Amendment does not raise any new issues for consideration by the Examiner; the Amendment reduces the number of issues on appeal, if necessary; and moreover, the Amendment is believed to place the application in condition for allowance.

The application is now believed to be in condition for allowance, and a notice to this effect is earnestly solicited.

If the Examiner is not fully convinced of all of the claims now in the application, applicant respectfully requests that the Examiner telephonically contact applicant's undersigned representative to expeditiously resolve prosecution of the application.

Favorable reconsideration is respectfully requested.